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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,097	04/13/2004	Steve J.D. Bell	13775/46204	6154

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,097	BELL, STEVE J.D.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-15-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 10-14-2008 are acknowledged. Claims 10 and 28 have been amended. Claims 31-33 have been added. Claims 10-12 and 27-33 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 7-15-2008 has been considered. An initialed copy is attached hereto.

Declaration

The declaration under 37 C.F.R. 1.132 by Edgar H. Relyveld filed on 10-14-2008 has been fully considered.

Priority

As parent application 09/496,771 does not disclose the use of calcium phosphate particles to deliver allergens, the filing date of application 09/932,538 (8-17-2001) will be used for determining the availability of art with regard to this limitation. Applicant's argument that the skilled artisan would know that an allergen is an immunogen is not germane. Since the parent application does not disclose or contemplate the use of allergens, it cannot provide support for instant claims 27 and 31-33.

Applicant's claim for priority with regard to claims 28-30 is deemed to be perfected in light of the amendment to claims 28. However, claim 27 and newly added claims are drawn to allergens which are unsupported by the parent application.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 10-11 and 28-29 under 35 U.S.C. 102(b) as being anticipated by Relyveld et al. (Annals of Allergy, 1985, Vol. 54, pages 521-529 – IDS filed on 10-21-2004) is maintained for reasons of record.

Applicant argues:

1. Relyveld et al. does not disclose that administration of "one or more smooth particles comprising calcium phosphate" or a method for producing said particles since the his particles (as per his declaration) are different than those of the instant invention.

2. While Dr. Relyveld did not explicitly refer to the cited reference his statement that he was unable to produce "substantially smooth" or "substantially spherical" particles necessarily encompasses the cited reference.

3. The limitation "...one or more surface irregularity is less than 100 nm." (claims 28 and 31) is not met by Relyveld.

Applicant's arguments have been fully considered and deemed non-persuasive

The specification does not define what constitutes a "smooth" particle. Given limitations set forth in amended claim 28 and newly added claim 31, to be a smooth particle a given particle needs only possess one irregularity that is less than 100 nm. Moreover, with regard to Dr. Relyveld's declaration, it is deemed to be unpersuasive as it does not address a smooth particle as engendered by the instant claims nor does it address the cited reference specifically.

As outlined previously, Relyveld et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 522). Moreover, Relyveld et al. disclose that said adsorbed particles were injected subcutaneously (see page 522). Additionally, with regard to the surface irregularity limitation of claim and 28 and 31, it is deemed in absence of evidence to the contrary that since the compositions of Relyveld et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Claims 10-11, 27-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ickovic et al. (Annals of Immunology (Inst. Pasteur), 1983, 134 D, pages 385-398 – IDS filed

on 10-21-2004) for the reasons set forth in the previous Office action in the rejection of claims 10-11 and 27-29

. **Applicant argues:**

1. Ickovic et al. does not disclose that administration of "one or more smooth particles comprising calcium phosphate" or a method for producing said particles since the his particles are different than those of the instant invention.

2. The limitation "...one or more surface irregularity is less than 100 nm." (claims 28 and 31) is not met by Ickovic et al..

Applicant's arguments have been fully considered and deemed non-persuasive

The specification does not define what constitutes a "smooth" particle. Given limitations set forth in amended claim 28 and newly added claim 31, to be a smooth particle a given particle needs only possess one irregularity that is less than 100 nm.

As outlined previously, Ickovic et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 387-.388). Moreover Ickovic et al. disclose that said adsorbed particles were injected subcutaneously (see page 387). Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Ickovic et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material,

structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Claims 10-11, 27-29 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuwayser (U.S. Patent 5,648,097 – IDS files on 10-21-2004) for the reasons set forth in the previous Office action in the rejection of claims 10-11 and 27-29.

Applicant argues:

1. Nuwayser discloses that their particles are formed via hydroforming and that said particles are non-uniform in shape and non-spherical and appear to be composed of interlocking crystals. Consequently, the particles of Nuwayser differ from the smooth particles of the instant invention. Applicant's arguments have been fully considered and deemed non-persuasive.

Contrary to Applicant's assertion, the particles of Nuwayser are disclosed to be "substantially uniform in shape, and preferably substantially spherical, and having a substantially smooth surface" (see column 3, lines 52-54). The portion of the specification cited by Applicant as characterizing the calcium phosphate particles of Nuwayser in fact was describing the characteristics of ground powders (see column 3, lines 54-60).

As outlined previously, Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens, desensitizing agents and antiallergenic (see column

6, lines 9-13). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 10-12 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Relyveld et al. (Annals of Allergy, 1985, Vol. 54, pages 521-529 – IDS filed on 10-21-2004) for the reasons set forth in previous Office action in the rejection of claims 10-12 and 27-30.

Applicant argues:

1. Relyveld et al. does not disclose that administration of "one or more smooth particles comprising calcium phosphate" or a method for producing said particles since the his particles (as per his declaration) are different than those of the instant invention.

2. While Dr. Relyveld did not explicitly refer to the cited reference his statement that he was unable to produce "substantially smooth" or "substantially spherical" particles necessarily encompasses the cited reference.

3. The limitation "...one or more surface irregularity is less than 100 nm." (claims 28 and 31) is not met by Relyveld.

Applicant's arguments have been fully considered and deemed non-persuasive

The specification does not define what constitutes a "smooth" particle. Given limitations set forth in amended claim 28 and newly added claim 31, to be a smooth particle a given particle needs only possess one irregularity that is less than 100 nm. Moreover, with regard to Dr. Relyveld's declaration, it is deemed to be unpersuasive as it does not address a smooth particle as engendered by the instant claims nor does it address the cited reference specifically.

As outlined previously, Relyveld et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 522). Moreover, Relyveld et al. disclose that said adsorbed particles were injected subcutaneously (see page 522). Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Relyveld et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Relyveld et al. differs from the instant invention in that he doesn't explicitly disclose the use of their calcium phosphate particles delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]).

Claims 10-12 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ickovic et al. (Annals of Immunology (Inst. Pasteur), 1983, 134 D, pages 385-398 – IDS filed on 10-21-2004) for the reasons set forth in the previous Office action in the rejection of claims 10-12 and 27-30..

Applicant argues:

1. Ickovic et al. does not disclose that administration of "one or more smooth particles comprising calcium phosphate" or a method for producing said particles since the his particles are different than those of the instant invention.

2. The limitation "…one or more surface irregularity is less than 100 nm." (claims 28 and 31) is not met by Ickovic et al..

Applicant's arguments have been fully considered and deemed non-persuasive

The specification does not define what constitutes a "smooth" particle. Given limitations set forth in amended claim 28 and newly added claim 31, to be a smooth particle a given particle needs only possess one irregularity that is less than 100 nm.

As outlined previously, Ickovic et al. disclose the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods (see abstract and page 387-.388). Moreover Ickovic et al. disclose that said adsorbed particles were injected

subcutaneously (see page 387). Additionally, with regard to the surface irregularity limitation of claim and 29, it is deemed in absence of evidence to the contrary that since the compositions of Ickovic et al. and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

Ickovic et al. differs from the instant invention in that he doesn't explicitly disclose the use of their calcium phosphate particles delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]).

Claims 10-12 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser (U.S. Patent 5,648,097 – IDS files on 10-21-2004) for the reasons set forth in the previous Office action in the rejection of claims 10-12 and 27-30.

Applicant argues:

1. Nuwayser discloses that their particles are formed via hydroforming and that said particles are non-uniform in shape and non-spherical and appear to be composed of interlocking crystals. Consequently, the particles of Nuwayser differ from the smooth particles of the instant invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

Contrary to Applicant's assertion, the particles of Nuwayser are disclosed to be "substantially uniform in shape, and preferably substantially spherical, and having a substantially smooth surface" (see column 3, lines 52-54). The portion of the specification cited by Applicant as characterizing the calcium phosphate particles of Nuwayser in fact was describing the characteristics of ground powders (see column 3, lines 54-60).

As outlined previously, Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens, desensitizing agents and antiallergenic (see column 6, lines 9-13). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*.

.Nuwayser differs from the instant invention in that he doesn't explicitly disclose the use of his "microparticles" delivered via inhalation or across a mucosal surface or that they are in the forms recited in claims 12 and 30.

However, given that utilization of biological products in said forms is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use said forms. (see *KSR*

International Co. v. Teleflex Inc., No. 04-1350 [U.S. Apr. 30, 2007]).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information

regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
February 1, 2009